

QUALITY ASSESSMENT DOCUMENT

PENNSYLVANIA DEPARTMENT OF HEALTH
BUREAU OF LABORATORIES
DIVISION OF LABORATORY IMPROVEMENT

CLIA #:		LABORATORY ID #:	
NAME OF LABORATORY:			
DATE OF SURVEY:	START TIME:	EXAMINER:	
PERSON(S) INTERVIEWED			
NAME:		TITLE:	
COMMENTS:			
REPEAT DEFICIENCIES:			
DIRECTOR PRESENT AT EXIT INTERVIEW: Y N			

D-TAGS	REQUIREMENTS			COMMENTS
ADMINISTRATIVE				
	A. Hours of Work <div style="text-align: center;"> M T W Th F Sa Su </div> From ----- To			
	B. Does the information in the STATE/CLIA system match (name, director, address, testing categories)? (Note: Review permit and certificate to ensure that they are current and accurate)	Y	N	
	C. Have there been any changes to the test menu (new test, instrument, or analyte put into use after April 24, 2003)?	Y	N	
	1. Does the lab have and follow policies and procedures for verifying performance specifications (accuracy, precision, reportable range, and normal values for patient populations) for any test system put into use after April 24, 2003?	Y	N	
	2. Did the lab notify the State prior to adding tests?	Y	N	
	<div style="text-align: center;"> <u>Test</u> <u>Instrument/Kit</u> <u>Complexity</u> <u>Volume</u> </div>			
	D. If the laboratory tests for creatinine, does it calculate and report the glomerular filtration rate?	Y	N	
	E. Have deficiencies from the previous survey been corrected?	Y	N	

D-TAGS	REQUIREMENTS			COMMENTS
	F. Does the laboratory perform testing for communicable diseases (e.g. Influenza, HIV, STD, Salmonella/Shigella, Lyme, RSV)?	Y	N	
	1. If yes, is the laboratory enrolled in the PA NEDSS for electronic processing of reportable conditions? (For additional information, go to www.health.state.pa.us)			
	G. Are high complexity tests performed?	Y	N	
	H. Does the laboratory director meet the personnel requirements for the complexity of testing performed? (Note: For labs performing high complexity testing, after February 24, 2003, a PhD director must have at least 2 years experience directing or supervising in a high complexity lab, or must be certified by a board approved by HHS)	Y	N	
	1. Does this individual direct more than 2 licensed laboratories?	Y	N	
	a. If yes, has an exception to Section 5.22 (f) of the state regulation been granted?	Y	N	
	2. Does the laboratory director specify in writing the responsibilities and duties of each individual involved in patient testing?	Y	N	
	3. Does the director ensure that technical/general supervisors and testing personnel meet the personnel requirements for the complexity of testing performed? (Note: After September 1, 1997, all new hires who will perform high complexity testing must possess an associates degree or equivalent unless they were performing high complexity testing before April 24, 1995)	Y	N	
	4. If there have been any changes in testing personnel, have they received appropriate training prior to testing patients' specimens? Documented?	Y	N	
	5. Does the lab follow written policies and procedures to assess employee competency? Documented?	Y	N	

D-TAGS	REQUIREMENTS			COMMENTS
	a. Are competency assessments performed semi-annually during the first year and annually thereafter?	Y	N	
PROFICIENCY TESTING (PT) ASSESSMENT				
	A. Which program(s) is the laboratory enrolled in?			
	1. Is the lab enrolled for all regulated analytes (CLIA requirement)?	Y	N	
	2. Is the lab enrolled for all tests performed in the lab for which PT specimens are available (State requirement)?	Y	N	
	3. Is the lab releasing PT results to the State?	Y	N	
	4. If the lab is licensed to perform Drugs of Abuse testing, Alcohol testing, or Lead testing, is the lab enrolled in the appropriate state proficiency testing program?	Y	N	
	B. Are PT specimens handled in the same manner as patient specimens?	Y	N	
	1. Are PT samples tested with the laboratory's regular workload by personnel who perform the testing?	Y	N	
	2. Do reagents or kits used for PT match those used for patient testing?	Y	N	
	3. Does the lab maintain the attestation statement certifying that PT samples were tested in the same manner as patient specimens?	Y	N	
	4. Are PT specimens tested the same number of times that patient specimens are tested? (Note: A PT specimen may only be run once unless specified by the lab's repeat criteria)	Y	N	
	5. Does the laboratory refrain from interlaboratory communication pertaining to PT results?	Y	N	

D-TAGS	REQUIREMENTS			COMMENTS
	6. Does the laboratory refrain from sending PT samples to another laboratory for analysis?	Y	N	
	a. Does the lab refrain from testing and/or reporting results if PT specimens are received from another lab?	Y	N	
	7. Does the lab maintain copies of all PT records for a minimum of 2 years, including a copy of the PT agency report form, any instrument printouts, and the graded results?	Y	N	
	C. Are PT results reviewed by the laboratory director? Documented?	Y	N	
	1. Does the lab evaluate the accuracy of any analyte that is not scored by the lab's PT program?	Y	N	
	D. Is corrective action taken for any PT result less than 100%? Documented?	Y	N	
	1. If PT results are less than 100%, does the lab determine if patient test results have been adversely affected? Documented?	Y	N	
	E. Does the laboratory evaluate, at least once every 6 months, tests for which no PT is performed or available? Documented? (Note: Alternative mechanisms to verify accuracy may include splitting samples with another laboratory or splitting samples among testing personnel in-house)	Y	N	
FACILITY ADMINISTRATION				
	A. Are space, ventilation, utilities, and safety protocols adequate for performing all phases of patient testing?	Y	N	
	B. Does the lab have appropriate and sufficient equipment, reagents, and supplies for the type and volume of testing performed?	Y	N	

D-TAGS	REQUIREMENTS			COMMENTS
	C. Does the lab ensure that reagents, kits, culture media, controls, calibrators, and other supplies are not used when they have exceeded their expiration date, have deteriorated, or are of substandard quality?	Y	N	
	D. Are all temperature-controlled areas monitored daily as needed? Documented?	Y	N	
	E. Does the lab retain the following records:			
	1. Test procedures for at least 2 years after they have been discontinued?	Y	N	
	2. Quality control and calibration records for at least 2 years? (immunohematology 5 years)	Y	N	
	3. Patient test records for at least 2 years (Including instrument printouts, unless the instrument is directly interfaced with an LIS)? (immunohematology 5 years)	Y	N	
	4. Maintenance logs for at least 2 years?	Y	N	
	5. Test/Instrument validation studies for the life of the instrument (but not less than 2 years)?	Y	N	
	6. Test reports at least 2 years after the date of reporting? (immunohematology 5 years, pathology 10 years)	Y	N	
	F. Has the laboratory made provisions to ensure that all records are maintained for the appropriate time frames if the laboratory ceases operation?	Y	N	
GENERAL LABORATORY SYSTEMS				
	A. Does the lab utilize a Laboratory Information System (LIS)?	Y	N	
	1. If yes, are procedures for computer use available?	Y	N	
	2. Is there a mechanism in place to prevent unauthorized access to patient sensitive data?	Y	N	
	3. Is there a mechanism in place to periodically verify that patient results are received as transmitted?	Y	N	

D-TAGS	REQUIREMENTS			COMMENTS
	4. Is there a mechanism in place to identify individuals entering patient data?	Y	N	
	5. If the lab stores requisitions and results electronically, can they assure that data has not been altered and is retrievable up to 2 years (immunohematology 5 years, pathology 10 years)?	Y	N	
	B. Does the lab ensure confidentiality of patient information throughout all phases of the testing process? (HIPAA)	Y	N	
	C. Does the lab have a system in place to ensure that it documents all complaints and problems reported to the lab?	Y	N	
	1. Are complaints investigated when appropriate?	Y	N	
	2. Are corrective actions taken? Documented?	Y	N	
PREANALYTIC SYSTEMS				
	A. Does the lab perform testing only when requested by an authorized person?	Y	N	
	B. What does the lab use as a test requisition?			
	1. Patient chart/Request form/Superbill?			
	C. Does the test requisition include the following information:			
	1. The name and address of the authorized person requesting the test(s)?	Y	N	
	2. The patient's name or other unique identifier?	Y	N	
	3. The sex and age (or date of birth) of the patient?	Y	N	
	4. The test(s) to be performed?	Y	N	
	5. The source of the specimen, when appropriate?	Y	N	
	6. The date, and, if appropriate, the time of specimen collection?	Y	N	

D-TAGS	REQUIREMENTS			COMMENTS
	7. Any additional information, if necessary, to ensure accurate reporting and interpretation of results?	Y	N	
	D. Does the lab have and follow a procedure manual or package insert(s) that includes written instructions for:			
	1. Patient identification?	Y	N	
	2. Patient preparation?	Y	N	
	3. Specimen collection?	Y	N	
	4. Specimen labeling?	Y	N	
	5. Specimen preservation?	Y	N	
	6. Specimen transport?	Y	N	
	7. Specimen processing?	Y	N	
	8. Specimen acceptability and specimen rejection?	Y	N	
	9. Specimen referral?	Y	N	
	E. Does the lab have a current client service manual for all reference labs to which specimens are sent?	Y	N	
	1. Does the lab have a mechanism to track which tests are still pending from their reference lab(s)?	Y	N	
	F. Does the lab supply a current client service manual (if acting as a reference lab)?	Y	N	
ANALYTIC SYSTEMS				
	A. Does the lab have and follow a written procedure or package insert for all tests performed (including microscopic examinations)? (Note: If a manufacturer's package insert is used as the procedure manual, it must be the most recent available)	Y	N	

D-TAGS	REQUIREMENTS			COMMENTS
	B. Did the director review, sign, and date procedures and changes in procedures before use?	Y	N	
	1. Has the procedure manual been reviewed/signed by all testing personnel?	Y	N	
	C. Does each procedure contain:			
	1. Step-by-step instructions with calculations and interpretations of results?	Y	N	
	2. Preparation and storage of materials used for testing?	Y	N	
	3. Calibration and calibration verification procedures?	Y	N	
	4. Reportable ranges?	Y	N	
	5. Control procedures?	Y	N	
	6. Corrective action that must be taken if calibration or control results fail to meet the lab's criteria for acceptability?	Y	N	
	7. Limitations, including interfering substances?	Y	N	
	8. Normal ranges?	Y	N	
	9. Panic values?	Y	N	
	10. References?	Y	N	
	11. The lab's system for reporting patient results, including the protocol for reporting a panic value?	Y	N	
	12. What to do if the test system is inoperable?	Y	N	
	D. Do test records include the following information:			
	1. The patient's name or unique identifier?	Y	N	
	2. The date and time the specimen was collected and/or received?	Y	N	
	3. The reason for specimen rejection, if applicable?	Y	N	

D-TAGS	REQUIREMENTS			COMMENTS					
	4. The date the test was performed?	Y	N						
	5. The identity of the person who performed the test(s)?	Y	N						
	E. If the lab performs the same test using different methodologies or instruments, is there a system in place that evaluates and defines the relationship between the methods at least twice a year?	Y	N						
	F. Does the lab have a policy that establishes values at which a test must be repeated and verified?	Y	N						
	CHEMISTRY								
	A. What subspecialties of chemistry are performed:								
	1. Routine Chemistry?	Y	N						
	2. Endocrinology?	Y	N						
	3. Toxicology?	Y	N						
	4. Other?	Y	N						
	B. Are manufacturer's calibration procedures being followed?	Y	N						
	<table border="0" style="width: 100%;"> <tr> <td style="text-align: left;"><u>Instrument</u></td> <td style="text-align: center;"><u>Analyte(s)</u></td> <td style="text-align: right;"><u>Date of Last Calibration</u></td> </tr> <tr> <td style="height: 100px;"></td> <td></td> <td></td> </tr> </table>	<u>Instrument</u>	<u>Analyte(s)</u>		<u>Date of Last Calibration</u>				
<u>Instrument</u>	<u>Analyte(s)</u>	<u>Date of Last Calibration</u>							

D-TAGS	REQUIREMENTS			COMMENTS
	<p>C. Are calibration verification procedures being performed according to manufacturer's instructions, but at least every 6 months at a minimal or zero value, a mid point value, and a maximum value near the upper limit of the reportable range?</p> <p>(Note: Calibration verification must also be performed if there is a complete change of reagents, there is major maintenance or replacement of critical parts, or if controls show a shift or trend)</p>	Y	N	
	<p>D. Are at least 2 levels of control material run each day of testing (or at the frequency specified by the manufacturer, if more stringent)?</p>	Y	N	
	<p>1. For non-waived test systems with procedural or electronic controls, has the laboratory evaluated control results using 2 levels of external controls for 30 consecutive days to determine the stability of the system?</p>	Y	N	
	<p>a. If the system has demonstrated stability, does the lab perform 2 levels of external controls each week of testing (and document procedural or electronic controls each day of testing)?</p>	Y	N	
	<p>2. For waived test systems with procedural or electronic controls, does the lab perform 2 levels of external controls each week of testing (and document procedural or electronic controls each day of testing)?</p>	Y	N	
	<p>3. Do all operators who perform testing perform quality control periodically?</p>	Y	N	
	<p>E. Do quality control records contain:</p>			
	<p>1. The date the control material was run?</p>	Y	N	

D-TAGS	REQUIREMENTS			COMMENTS
	2. All control results, whether in range or not?	Y	N	
	3. Ranges of acceptable control values?	Y	N	
	4. Documentation of corrective action?	Y	N	
	5. Indication of date of opening for reagents, controls, and calibrators?	Y	N	
	6. Expiration dates and lot numbers of reagents, controls, and calibrators? (Note: Reagents, controls, and calibrators must not be used when they have exceeded their expiration date)	Y	N	
	F. Are maintenance/function checks performed as per manufacturer's instructions? Documented?	Y	N	
	G. Whole Blood Glucose Testing:			
	Instrument used:			
	1. Are 2 levels of external liquid control performed each day of testing?	Y	N	
	2. Is the electronic control performed as per manufacturer's instructions, if applicable?	Y	N	
	H. Do quality control records contain:			
	1. The date the control material was run?	Y	N	
	2. All control results, whether in range or not?	Y	N	
	3. Ranges of acceptable control values?	Y	N	
	4. Documentation of corrective action?	Y	N	
	5. Indication of date of opening for test strips and controls?	Y	N	

D-TAGS	REQUIREMENTS			COMMENTS
	6. Expiration dates and lot numbers of test strips and controls? (Note: Test strips and controls must not be used when they have exceeded their expiration date)	Y	N	
	I. Blood Gas Testing:			
	1. Are calibration and calibration verification procedures performed as per manufacturer's instructions?	Y	N	
	2. Is one control material run each 8-hour shift using a combination of control materials that includes both low and high values each day of testing? (Note: If the instrument does not internally verify calibration at least every 30 minutes, the lab must include one sample of calibrator/control material each time patients are tested)	Y	N	
	J. Do quality control records contain:			
	1. The date the control material was run?	Y	N	
	2. All control results, whether in range or not?	Y	N	
	3. Ranges of acceptable control values?	Y	N	
	4. Documentation of corrective action?	Y	N	
	5. Indication of date of opening for reagents and controls?	Y	N	
	6. Expiration dates and lot numbers of reagents and controls? (Note: Reagents and controls must not be used when they have exceeded their expiration date)	Y	N	
	K. Are maintenance/function checks performed as per manufacturer's instructions? Documented?	Y	N	
	L. Drug Screen Kits:			
	1. Are a positive and a negative control material run each day of testing (or at the frequency specified by the manufacturer, if more stringent)?	Y	N	

D-TAGS	REQUIREMENTS			COMMENTS
	2. For non-waived test systems with procedural or electronic controls, has the laboratory evaluated control results using positive and negative external controls for 30 consecutive days to determine the stability of the system?	Y	N	
	a. If the system has demonstrated stability, does the lab perform a positive and a negative external control each week of testing (and document procedural or electronic controls each day of testing)?	Y	N	
	3. For waived test systems, does the lab follow manufacturer's quality control instructions? (Note: All quality control must be documented, including internal controls)	Y	N	
	URINALYSIS			
	A. Extent of testing performed:			
	1. Dipsticks only?	Y	N	
	2. Dipsticks plus microscopic?	Y	N	
	a. Does the lab follow a standardized procedure for urine microscopics?	Y	N	
	3. Automated strip reader?	Y	N	
	a. Are maintenance/function checks performed as per manufacturer's specifications? Documented?	Y	N	
	B. For waived tests, does the lab perform a positive control for each dipstick constituent reported each week of testing and when a new lot is put into use?	Y	N	
	C. For non-waived tests, does the lab perform a positive and a negative control each day of testing (or at the frequency specified by the manufacturer, if more stringent)?	Y	N	

D-TAGS	REQUIREMENTS			COMMENTS
	D. If the lab uses a refractometer or urinometer for measuring specific gravity, is it calibrated each week of use with both a high and a low material?	Y	N	
	E. Do quality control records contain:			
	1. The date the control material was run?	Y	N	
	2. All control results, whether in range or not?	Y	N	
	3. Ranges of acceptable control values?	Y	N	
	4. Documentation of corrective action?	Y	N	
	5. Indication of date of opening for dipsticks and controls?	Y	N	
	6. Expiration dates and lot numbers of dipsticks and controls? (Note: Dipsticks and controls must not be used when they have exceeded their expiration date)	Y	N	
	MICROBIOLOGY			
	A. Extent of testing performed:			
	1. Bacteriology?	Y	N	
	2. Mycology?	Y	N	
	3. Parasitology?	Y	N	
	4. Virology?	Y	N	
	B. Throat Culture:			
	1. Media Used:			
	2. Is a visual inspection performed on each shipment/lot of media? Documented?	Y	N	

D-TAGS	REQUIREMENTS			COMMENTS
	3. Is media QC performed (in-house/by a reference lab/by the manufacturer)? Documented?	Y	N	
	4. If Bacitracin (A) discs are used, does the lab test each lot/shipment of discs using a Group A strep and a non-Group A strep?	Y	N	
	C. Do quality control records contain:			
	1. The date the control material was run?	Y	N	
	2. All control results, whether acceptable or not?	Y	N	
	3. Expected control results?	Y	N	
	4. Documentation of corrective action?	Y	N	
	5. Indication of date of opening for discs?	Y	N	
	6. Expiration dates and lot numbers of discs? (Note: Discs must not be used when they have exceeded their expiration date)	Y	N	
	D. Throat Screens:			
	1. Rapid Strep kit(s) used:			
	2. For non-waived Strep kits, does the lab perform a positive and a negative external control each day of testing? Documented?	Y	N	
	a. For test systems with internal procedural controls, has the laboratory evaluated control results using positive and negative external controls for 30 consecutive days to determine the stability of the system?	Y	N	

D-TAGS	REQUIREMENTS			COMMENTS
	b. If the system has demonstrated stability, does the lab perform a positive and a negative external control each week of testing (and document procedural or internal controls each day of testing)?	Y	N	
	3. For waived strep kits, does the lab follow manufacturer's quality control instructions? (Note: All quality control must be documented, including internal controls)	Y	N	
	E. Do quality control records contain:			
	1. The date the control material was run?	Y	N	
	2. All control results?	Y	N	
	3. Documentation of corrective action?	Y	N	
	4. Indication of date of opening for kits and controls?	Y	N	
	5. Expiration dates and lot numbers of kits and controls? (Note: Kits and controls must not be used when they have exceeded their expiration date)	Y	N	
	F. Urine Cultures:			
	1. Media used:			
	2. When reporting urine culture results, does the lab report: ___ Colony Count (No PT req'd) ___ Organism ID ___ Growth/No Growth ___ Susceptibility ___ Presumptive ID			
	3. Is a visual inspection performed on each shipment/lot of media? Documented?	Y	N	

D-TAGS	REQUIREMENTS			COMMENTS
	4. Is media QC performed (in-house/by a reference lab/by the manufacturer)? Documented? (Note: Media commercially prepared and packaged as a unit or test system consisting of 2 or more different substrates primarily used for microbial ID must be QC'd by the user lab)	Y	N	
	G. Susceptibility Testing on Pure Culture:			
	1. Is Mueller Hinton Media used? (Note: Mueller Hinton media must have end-user QC)	Y	N	
	2. Is there a desiccant in the disc dispenser?	Y	N	
	3. Is a barium sulfate turbidity standard used to prepare the inoculum? (Note: The BBL Prompt system is a satisfactory substitute)	Y	N	
	a. Is the barium sulfate standard in-date?	Y	N	
	4. Are discs stored according to manufacturer's instructions?	Y	N	
	5. Is disc quality control performed each day of testing with <i>S. aureus</i> , <i>E. coli</i> and <i>Ps. aeruginosa</i> as appropriate? (Note: After a 30 day validation, disc QC may be performed each week of testing)	Y	N	
	H. Do quality control records contain:			
	1. The date the control material was run?	Y	N	
	2. All control results, whether in range or not?	Y	N	
	3. Ranges of acceptable control values?	Y	N	
	4. Documentation of corrective action?	Y	N	
	5. Indication of date of opening for discs?	Y	N	
	6. Expiration dates and lot numbers of discs? (Note: Discs must not be used when they have exceeded their expiration date)	Y	N	

D-TAGS	REQUIREMENTS			COMMENTS
	I. Direct Susceptibility Testing:			
	1. Is disc QC performed each day of testing with all 3 organisms? (Note: 30 day validation is not an option)	Y	N	
	J. Gram Stains:			
	1. Specimen source: ___ Genital (Moderate Complexity) ___ Other (High Complexity)			
	2. Are Gram stain reagents checked each week of use with a known Gram positive organism and a known Gram negative organism?	Y	N	
	K. Do quality control records contain:			
	1. The date the control material was run?	Y	N	
	2. All control results, whether acceptable or not?	Y	N	
	3. Expected control results?	Y	N	
	4. Documentation of corrective action?	Y	N	
	5. Indication of date of opening for stains and controls?	Y	N	
	6. Expiration dates and lot numbers of stains and controls? (Note: Stains and controls must not be used when they have exceeded their expiration date)	Y	N	
	L. Rapid Virology Kits (RSV, Rotavirus, Influenza):			
	1. Kit(s) used:			

D-TAGS	REQUIREMENTS			COMMENTS
	2. For non-waived test kits, does the lab perform a positive and a negative external control each day of testing? Documented?	Y	N	
	3. For waived test kits, does the lab follow manufacturer's quality control instructions? (Note: All quality control must be documented, including internal controls)	Y	N	
	M. Do quality control records contain:			
	1. The date the control material was run?	Y	N	
	2. All control results, whether acceptable or not?	Y	N	
	3. Documentation of corrective action?	Y	N	
	4. Indication of date of opening for kits and controls?	Y	N	
	5. Expiration dates and lot numbers of kits and controls? (Note: Kits and controls must not be used if they have exceeded their expiration date)	Y	N	
	HEMATOLOGY			
	A. Instrument(s) used:			
	1. Are manufacturers' calibration procedures being followed?	Y	N	
	2. Is a background count performed each day of testing? Documented?	Y	N	
	3. Are at least 2 levels of control material run each day of testing (or at the frequency specified by the manufacturer, if more stringent)?	Y	N	
	B. Do quality control records contain:			
	1. The date the control material was run?	Y	N	
	2. All control results, whether in range or not?	Y	N	

D-TAGS	REQUIREMENTS			COMMENTS
	3. Ranges of acceptable control values?	Y	N	
	4. Documentation of corrective action?	Y	N	
	5. Indication of date of opening for reagents, controls, and calibrators?	Y	N	
	6. Expiration dates and lot numbers of reagents, controls, and calibrators? (Note: Reagents, controls, and calibrators must not be used when they have exceeded their expiration date)	Y	N	
	C. Are maintenance/function checks performed as per manufacturer's instructions? Documented?	Y	N	
	D. Differential Smears:			
	1. Stain used:			
	a. Does the lab record the lot number and expiration date of the stain?	Y	N	
	2. Are there written criteria for review of abnormal smears by a qualified person?	Y	N	
	E. Hemocue:			
	1. Is the control cuvette (calibrator) run each day of testing?	Y	N	
	2. Is at least one abnormal liquid control run each week of testing?	Y	N	
	F. Do quality control records contain:			
	1. The date the control material was run?	Y	N	
	2. All control results, whether in range or not?	Y	N	
	3. Ranges of acceptable control values?	Y	N	
	4. Documentation of corrective action?	Y	N	
	5. Indication of date of opening for cuvettes and controls?	Y	N	

D-TAGS	REQUIREMENTS			COMMENTS
	6. Expiration dates and lot numbers of cuvettes and controls? (Note: Cuvettes and controls must not be used when they have exceeded their expiration date)	Y	N	
	G. Hemoglobin (Other):			
	1. Are at least 2 levels of control material run each day of testing (or at the frequency specified by the manufacturer, if more stringent)?	Y	N	
	2. For non-waived test systems with procedural or electronic controls, has the laboratory evaluated control results using 2 levels of external controls for 30 consecutive days to determine the stability of the system?	Y	N	
	a. If the system has demonstrated stability, does the lab perform 2 levels of external controls each week of testing (and document procedural or electronic controls each day of testing)?	Y	N	
	3. For waived test systems with procedural or electronic controls, does the lab perform 2 levels of external controls each week of testing (and document procedural or electronic controls each day of testing)?	Y	N	
	H. Do quality control records contain:			
	1. The date the control material was run?	Y	N	
	2. All control results, whether in range or not?	Y	N	
	3. Ranges of acceptable control values?	Y	N	
	4. Documentation of corrective action?	Y	N	
	5. Indication of date of opening for reagents and controls?	Y	N	

D-TAGS	REQUIREMENTS			COMMENTS
	6. Expiration dates and lot numbers of reagents and controls? (Note: Reagents and controls must not be used when they have exceeded their expiration date)	Y	N	
	I. Microhematocrit:			
	1. Is the microhematocrit procedure verified with controls or Proficiency Testing?	Y	N	
	J. Manual Cell Counts (WBC, RBC, Platelets, Retics):			
	1. Are manual cell counts performed using a hemocytometer tested in duplicate? Documented?	Y	N	
	2. Is one control material performed each 8-hour shift? Documented?	Y	N	
	K. Coagulation (including ACT Testing):			
	1. Instrument used:			
	2. How is the Prothrombin Time reported: Seconds INR Seconds/INR % (Percent)			
	3. Is the lab using the ISI value from the current manufacturer's package insert?	Y	N	
	4. For non-waived instruments, does the lab run 2 levels of liquid control material each 8-hour shift and with each change of reagent (or at the frequency specified by the manufacturer, if more stringent)? (Note: Non-waived instruments with electronic or procedural controls are eligible for EQC option 2)	Y	N	

D-TAGS	REQUIREMENTS			COMMENTS
	5. For waived instruments, if electronic controls are available from the manufacturer, does the lab run the electronic controls each day of testing and 2 levels of external liquid control each week of testing?	Y	N	
	L. Do quality control records contain:			
	1. The date the control material was run?	Y	N	
	2. All control results, whether in range or not?	Y	N	
	3. Ranges of acceptable control values?	Y	N	
	4. Documentation of corrective action?	Y	N	
	5. Indication of date of opening for reagents and controls?	Y	N	
	6. Expiration dates and lot numbers of reagents and controls? (Note: Reagents, and controls must not be used when they have exceeded their expiration date)	Y	N	
	M. Are maintenance/function checks performed as per manufacturer's instructions? Documented?	Y	N	
	IMMUNOLOGY			
	A. Instruments/kits used:			
	B. For non-waived test systems, are a positive and a negative external control run each day of testing and with each new lot (or at the frequency specified by the manufacturer, if more stringent)?	Y	N	

D-TAGS	REQUIREMENTS			COMMENTS
	1. For test systems with internal procedural controls, has the lab evaluated control results using positive and negative external controls for 30 consecutive days to determine the stability of the system?	Y	N	
	a. If the system has demonstrated stability, is the lab performing a positive and a negative external control each week of testing (and documenting internal procedural controls each day of testing)?	Y	N	
	C. For waived test systems, does the lab follow manufacturer's quality control instructions? (Note: All quality control must be documented, including internal controls)	Y	N	
	D. Do quality control records contain:			
	1. The date the control material was run?	Y	N	
	2. All control results, whether in range or not?	Y	N	
	3. Ranges of acceptable control values?	Y	N	
	4. Documentation of corrective action?	Y	N	
	5. Indication of date of opening for kits, reagents, and controls?	Y	N	
	6. Expiration dates and lot numbers of kits, reagents, and controls? (Note: kits, reagents, and controls must not be used when they have exceeded their expiration date)	Y	N	
	E. Are maintenance/function checks performed as per manufacturer's instructions? Documented?	Y	N	
POSTANALYTIC SYSTEMS				
	A. Do Test Reports include the following:			
	1. Positive patient identification (either the patient's name and/or ID number, or a unique patient identifier)?	Y	N	
	2. The name and address of the laboratory where the test was performed?	Y	N	

D-TAGS	REQUIREMENTS			COMMENTS
	3. The test report date?	Y	N	
	4. The test performed?	Y	N	
	5. Specimen source, when appropriate?	Y	N	
	6. The test result and, if applicable, the units of measurement?	Y	N	
	7. Reason for specimen rejection, if applicable?	Y	N	
	B. Are reference or normal ranges available to the person using the test results?	Y	N	
	C. Does the test reporting procedure ensure that patient test results are reported in a timely manner?	Y	N	
	D. Does the test reporting system ensure that test results are released to and received by only authorized persons?	Y	N	
	E. Are corrected results specified as such on all reports?	Y	N	
QUALITY ASSESSMENT				
	A. Does the lab have policies and procedures for assessing each phase of the total testing process?	Y	N	
	1. Does the lab document all quality assessment activities?	Y	N	
	B. Does the lab investigate and document every instance in which a quality indicator is outside of expected limits?	Y	N	
	C. Does the lab retain all quality assessment records for at least 2 years?	Y	N	